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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,920	06/19/2000	Lawrence E. Samelson	NIH-05065	4586

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KAMRIN T. MACKNIGHT
MEDLEN & CARROLL, LLP
101 HOWARD STREET, SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,920	SAMELSON ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 26-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group II, claims 4-6 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 29-37 have been added.

Claims 1-3 and 7-25 have been cancelled.

Claims 4-6 and 26-37 are pending and under examination.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

a. Non-initialed and/or non-dated alterations have been made to the oath or declaration with regard to the inventors citizenship and inventors Zhang's residence and post office address. See 37 CFR 1.52(c).

Specification

4. The disclosure is objected to because of the following informalities:

a. The first line of the specification should be updated to indicate that this application claims benefit to provisional application 60/068,890, filed 12/23/97 and the

first line should indicate that "This is a continuation of International Application PCT/US98/27400, with an international filing date of December 23, 1998, published in English under PCT Article 21(2) and now abandoned." (see MPEP 1895.01)

Appropriate correction is required.

Sequence Requirements

5. Although an action on the merits could be performed on this application in order for compact prosecution, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) see for example on page 58, lines 24 and 26.

Any questions regarding compliance with the sequence rules requirements Specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 27, 28, 31, 32, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claims 27, 28, 31, 32, 35, and 36 recite wherein the portion comprises amino acids 23 to 233 or 1 to 22. The response filed 1/4/02 states that support for the claims can be found "throughout the Specification (See e.g., pages 5-6, 38-41, 56-57, 63-64, etc)" (see page 4 of response). In response to this the examiner apparently finds no support for the recited limitations of the amino acids 23 to 233 or 1 to 22. It is noted that the specification teaches that "the cytosolic domain is defined approximately by amino acids 28-233" (see page 54, lines 27-28). Applicants are required to provide specific support for the limitations in the specification as originally filed or remove them from the claims.

Priority

8. The Examiner acknowledges applicants request for priority to provisional application 60/068,690 and PCT/US98/27400, however, the limitations recited in claims 27, 28, 31, 32, 35, and 36 which recites wherein said portion comprises amino acids 23-233 or 1-22 are not seen in the priority documents. As such claims 27, 28, 31, 32, 35, and 36 are granted the priority date of the instant application.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 4, 6, 26-29, 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Buday et al (The Journal of Biological Chemistry 269:9019-9023, 1994, IDS #5) and as evidenced from the specification.

The claims recite an antibody that binds specifically to a polypeptide comprising a portion of amino acids 23-233, 28-233, 1-22 or directed against SEQ ID NO:4 wherein the antibody is monoclonal.

Buday et al teach a monoclonal antibody 4G10 that is an anti-phosphotyrosine antibody and the antibody binds to the p36 protein (see Figure 4A). Buday et al teach the protein p36 which is a 36 kDa protein that is phosphorylated and membrane bound and is associated with TCR (see abstract and page 9022). The specification discloses a 36 kDa polypeptide that is phosphorylated by ZAP-70 and that is associated with T cell receptors (see page 66 and 68 of specification). Because of the open language of the term "comprising" the claims are interpreted to mean the recited amino acid portions plus other amino acids which reads on the entire protein which would contain tyrosine residues that are phosphorylated. Since Buday teach a anti-phosphotyrosine antibody, the protein is phosphorylated, and as disclosed in the specification that the protein is phosphorylated, therefore the antibody of Buday et al would specifically bind to SEQ ID NO:4. In addition, because the term "specifically" is not defined in the specification and the term "portion" can be interpreted to mean any part of an amino acid sequence or an amino acid, the art of Buday et al reads on the claims.

It is the Examiner's position that Buday et al have produced an antibody that is directed to the same antigen as recited in the claims even though Buday et al does not

disclose the amino acid sequence of SEQ ID NO:4. One would reasonably envisage that Buday et al's protein is the same as that in the instant application because of similar properties such as similar molecular weight, a phosphorylated protein, associated with T cell receptor and, therefore, it appears that Buday et al have produced an antibody that would specifically bind to SEQ ID NO:4. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody or the claimed antigen SEQ ID NO:4 with the antibody and the antigen of Buday et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antigen and the antibody and the antigen of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

11. Claim 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al (Cell 92:83-92, 1998, IDS #5).

Claim 31 and 32 recites a polyclonal antibody directed against a portion of SEQ ID NO:4 wherein the portion comprises amino acids 23-233 or 1-22.

Zang et al teach a rabbit anti-LAT antibody (see Figure 2) which was generated against residues 31-233 of LAT (see Experimental Procedures) which is directed against the LAT protein which is identical to SEQ ID NO:4 (see Figure 1D). Because of the open language in the term "comprising" the claims are interpreted to encompass the entire sequence of SEQ ID NO:4.

12. Claims 31, 32, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al (The Journal of Experimental Medicine 187:1157-1161, 1998).

The claims have been described supra.

Weber et al teach polyclonal antibodies to SEQ ID NO:4 (pp36 is identical to SEQ ID NO:4) as well as an anti-phosphotyrosine monoclonal antibody (see page 1158 of Materials and Methods). Because of the open language in the term "comprising" the claims are interpreted to encompass the entire sequence of SEQ ID NO:4 which encompasses tyrosine residues which are phosphorylated. Therefore, since the protein contains residues that are phosphorylated (as evidenced above in the rejection of Buday et al) the monoclonal antibody of Weber would specifically bind to the polypeptide as indicated by Weber (See page 1158, 2nd paragraph, left column).

13. Claims 4-5, 26-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirth et al (U.S. Patent 5,958,959, filed 6/1/95).

Claims 4, 26-29, 31-32 have been described supra. Claims 5, 30, and 33 recite wherein the antibody is a polyclonal antibody directed against a portion comprising amino acids 28-233 of SEQ ID NO:4 and directed against SEQ ID NO:4.

Hirth et al teach a polyclonal antiphosphotyrosine antibody (see column 25, line 50). As evidenced in the specification the protein of SEQ ID NO:4 is phosphorylated

and can be detected with anti-phosphotyrosine antibodies (see page 67, lines 14-16 and page 70, lines 18-19). Because the protein is phosphorylated and due to the open language of "comprising" which encompasses the entire protein which includes residues phosphorylated (tyrosine) and because of the term "portion" which encompasses any part of an amino acid sequence or an amino acid, the art of Hirth et al reads on the claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (Cell 92:83-92, 1998, IDS #5) and further in view of Campbell (Monoclonal antibody Technology, Elsivier Science Pub., NY, Chapter 1, pages 1-32).

The claim has been described supra.

Zhang et al has been described supra. Zhang et al does not tech a monoclonal antibody directed against LAT. This deficiency is made up for in the teachings of Campbell.

Campbell teach production of monoclonal antibodies to proteins.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to produce polyclonal antibodies as taught by Campbell to the LAT protein of Zhang et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to produce polyclonal antibodies as taught by Campbell to the LAT protein of Zhang et al because Zhang et al teach antibodies to LAT and Campbell et al teach the advantages of monoclonal antibodies in detection and therapeutics and Campbell teach that "It is customary now for any group working on a

macromolecule to both clone the genes coding for it and make monoclonal antibodies to it" (see page 29).

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879